



Our Reference: UMJ-103-B (UM 1667)

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Peter X. Ma et al.
Serial Number: 09/936,692
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Examiner/Art Group Unit: Peter A. Szekely/1714
Title: IONOMER COMPOSITE COMPOSITIONS

DECLARATION PURSUANT TO 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Peter X. Ma, hereby declare the following:

1. I am a co-inventor of the above-identified application.
2. I am a citizen of the United States residing at 3208 Foxway Court, Ann Arbor, Michigan 48105.
3. I received a Bachelor of Science in Polymer Chemistry and a Master of Science in Polymer Materials from Tsinghua University in Beijing, China.
4. I received a Master of Science and a Ph.D in Polymer Science and Engineering from Rutgers University, New Brunswick, New Jersey, in 1993.
5. I performed post doctorate work at MIT in Cambridge, Massachusetts, from 1993-1996 in Biomaterials and Tissue Engineering.
6. I joined the University of Michigan in 1996 as a professor and have engaged in the research of polymeric biomaterials, tissue engineering, ion-containing polymers, and biomechanics since then. I have worked on development and structure-property relationship studies of polymer systems of biomedical importance, such as bioactive polymer materials, biodegradable polymers and mechanically superior polymeric multiphase

materials. Further, I have worked on understanding polymer-cell interactions, and the signal and substrate requirements for cell proliferation and tissue regeneration in three dimensions to create functional tissues. Regarding biomechanics, I have studied the biomechanical behavior of engineered tissues in relation to biochemical composition, morphology and function and the effects of mechanical stimulation on tissue regeneration on three-dimensional polymer scaffolds.

7. After reviewing the cited references (Tezuka, 4,089,830; Wilson, 4,569,954; Wilson, 4,758,612; Okabayashi, 5,051,453; Kato, 5,520,725; Englebrecht, 4,872,936; and National Res Dev Corp GB 1,507,981), I submit that all of the references teach cement compositions, which are water soluble compositions.

8. In the exemplary materials listed therein, the cited references do not distinguish between those which are water soluble (hydrophilic) compositions and those which are water insoluble (hydrophobic) compositions, nor do they distinguish between compositions that will properly function as dental cement and those that will not properly function as dental cement.

9. I performed experiments or research, as shown below, based on the teachings of the cited references to show that certain compositions as taught by the cited references would not function as dental cement because they do not dissolve in water.

10. I determined the solubility of several copolymers, as listed in Table 1 attached as Exhibit 1. One series of copolymers included 0%, 5%, 10%, 20%, 25%, and 100% methyl acrylic acid hydrophilic monomer and 100%, 95%, 90%, 80%, 75% and 0% methyl methacrylate hydrophobic monomer (as taught in Englebrecht 4,872,936). The other series of copolymers included 50% acrylic acid hydrophilic monomer and 50% ethyl acrylate or n-butyl acrylate hydrophobic monomer (as taught in Okabayashi, 5,051,453).

11. I tested the solubility of the methyl methacrylate/methyl acrylic acid compositions via the following method. 50 +/- 0.5 mg of the polymer(s) was added to 5 mL water to obtain a mixture or solution of 1% polymer(s). After two days, the mixture or solution was centrifuged and the supernatant was removed. The remaining polymer(s) was dried in a vacuum oven over night. If the weight change of the remaining polymer(s) was less than 1 mg when compared to the original polymer(s), then the polymer(s) was not considered to be soluble in water.

12. I determined the solubility of the ethyl acrylate/acrylic acid composition and the n-butyl acrylate/acrylic acid directly from the manufacturer.

13. Exhibit 1 depicts the copolymers and their solubility. The results indicate that the homo polymer methyl acrylic acid composition (i.e. 0% hydrophobic monomer) is water soluble. The other copolymers are not water soluble and therefore would not function as dental cement, contrary to the stated purpose of the '936 and '453 patents.

14. I submit that the results prove that the cited art does not distinguish in their exemplary lists between those compositions that properly function and those compositions that do not properly function as dental cements.

15. Further, I submit that one skilled in the art, upon reviewing my above-identified specification, would know that the ratio of hydrophilic monomer to hydrophobic monomer is measured in mole percents.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and, that such willful false statements may jeopardize the validity of the application or any patent issued thereon.


Peter X. Ma

9-13-2004
Date



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Exhibit 1

Table 1. Solubility of Certain Copolymers in Water

Acrylate (A)	Acid (B)	Ratio (A/B)	Solubility in H ₂ O
Methyl methacrylate	Methyl acrylic acid	100/0	No
Methyl methacrylate	Methyl acrylic acid	95/5	No
Methyl methacrylate	Methyl acrylic acid	90/10	No
Methyl methacrylate	Methyl acrylic acid	80/20	No
Methyl methacrylate	Methyl acrylic acid	75/25	No
Methyl methacrylate	Methyl acrylic acid	0/100	Yes
Ethyl acrylate	Acrylic acid	50/50	No
n-Butyl acrylate	Acrylic acid	50/50	No